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"Patient Privacy": The Illusory Barrier to Fixing Missouri's Opioid Overdose Problem

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“PATIENT PRIVACY”: THE ILLUSORY BARRIER TO FIXING MISSOURI’S OPIOID OVERDOSE PROBLEM

*Charlie McKiver**

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INTRODUCTION

For much of the twentieth century, doctors only recognized pain as a symptom, never as an illness in itself.¹ As a result, doctors prescribed opioids, such as morphine and oxycodone, to treat short-term pain, but not to treat chronic pain.² Then, in the 1970s, medical professionals became more interested in managing pain and they began to view chronic pain as an illness in itself.³ Although perceptions of chronic pain changed, the prescription drugs available to treat this illness did not, and doctors remained hesitant to treat chronic pain with highly addictive opioids.⁴

However, things changed in 1996 when pharmaceutical company Purdue Frederick obtained FDA approval for OxyContin, a time-release, less addictive oxycodone pill intended to treat chronic pain.⁵ Purdue Frederick marketed OxyContin as “difficult to abuse,” in an effort to assuage doctors’ fears.⁶ Due to this marketing, prescriptions of opioids quickly skyrocketed, but unfortunately, so did accidental opioid overdoses.⁷

Despite Purdue Frederick’s claims, OxyContin (and other opioid analgesics) was actually highly susceptible to abuse because it could be “crushed, then swallowed, snorted, or injected for a powerful high.”⁸ Several states and individuals sued Purdue Frederick for misbranding OxyContin as a non-addictive drug.⁹ The company ultimately pled guilty to a felony charge of misbranding and paid over \$600 million in fines.¹⁰ But no fine could remedy the destruction caused by the drug and the nation is still burdened by opioid abuse.

¹ Ian Frazier, *The Antidote: Can Staten Island’s Middle-Class Neighborhoods Defeat An Overdose Epidemic?*, NEW YORKER (Sept. 8, 2014), <http://www.newyorker.com/magazine/2014/09/08/antidote>.

² *Id.*; see also Chronic Pain: Symptoms, Diagnosis & Treatment, 6 NIH MEDLINE PLUS 1, 5-6 (2011), <http://www.nlm.nih.gov/medlineplus/magazine/issues/spring11/articles/spring11pg5-6.html> (explaining that short-term pain lasts no longer than twelve weeks and occurs during recovery from an injury or procedure or during the progression of terminal illness, while chronic pain is “any pain lasting more than 12 weeks”).

³ Frazier, *supra* note 1.

⁴ See *A Nation in Pain: Focusing On U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain* 1, 4, EXPRESS SCRIPTS LAB (Dec. 2014), <http://lab.express-scripts.com/publications/a-nation-in-pain> (explaining that doctors were reluctant to prescribe opioids because it is easy for patients to become addicted to them, as the body can build up a tolerance to opioid drugs and such drugs do not have a maximum clinically safe dosage limit) (hereinafter *A Nation in Pain*).

⁵ Frazier, *supra* note 1.

⁶ *Id.*

⁷ See Alexandra Sifferlin, *The Problem with Treating Pain in America*, TIME (Jan. 12, 2015), <http://time.com/3663907/treating-pain-opioids-painkillers/> (explaining that the number of opioid prescriptions for pain has almost tripled, from 76 million to 219 million between 1991-2011, and the number of hospitalizations and deaths related to opioid addiction has also increased dramatically).

⁸ Frazier, *supra* note 1.

⁹ *Id.*

¹⁰ *Id.*; Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html?_r=0.

Prescription opioid overdose death rates quadrupled from 1999-2013.¹¹ During this period, almost fifty Americans died from prescription drug overdoses daily.¹² Today, Americans make up less than 5% of the world's population, but consume more than 80% of the world's opiate supply.¹³ Opioid abuse has also imposed significant costs on the American economy.¹⁴ Fortunately, the United States recently experienced the first reduction in opioid overdose deaths in over a decade.¹⁵ And some states, like Florida, have seen a dramatic decrease in overdose deaths, largely because of their initiatives aimed at curtailing opioid overprescribing.¹⁶

The most successful of these initiatives have been Prescription Drug Monitoring Programs (PDMPs), which are electronic databases that monitor opioid prescriptions. Because PDMPs have proven to both curb medically unnecessary opioid prescriptions and reduce opioid mortality, all but one state legislature has enacted legislation to create a PDMP.¹⁷ The lone holdout is the state of Missouri. Although residents of seven neighboring states with PDMPs travel to Missouri to procure opioids and Missouri has become known as "America's Drug Store," its legislature has refused to establish a PDMP.¹⁸ Conservative lawmakers in Missouri cite patient privacy concerns for their past refusal to pass a PDMP. In March of 2015, the state's senate passed a bill authorizing a PDMP, but it contained numerous measures designed to protect patient privacy. The Missouri senate bill was ultimately not enacted into law, but this Article will argue that Missouri legislators' concerns about patient privacy are not compelling.

This Article will explain why the Missouri state legislature should pass a statute to authorize a PDMP. It will then outline why drafting a robust and effective PDMP will not violate the Constitution, or federal and state privacy regulations.

¹¹ *Injury Prevention and Control: Prescription Drug Overdose*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/drugoverdose/data/index.html>.

¹² *Id.*

¹³ *A Nation in Pain*, *supra* note 4 at 4.

¹⁴ *Id.* (including \$42 billion in lost productivity, \$8.2 billion in increased criminal justice costs, \$2.2 billion for drug abuse treatment, and \$944 million in medical complications).

¹⁵ Margaret Warner, Holly Hedegaard, & Li-Hui Chen, *Trends in Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 1999-2012*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Dec. 2014), http://www.cdc.gov/nchs/data/hestat/drug_poisoning/drug_poisoning.htm (reporting a 5% decline in opioid-analgesic overdose deaths between 2011 and 2012).

¹⁶ See Hal Johnson et al., *Decline in Drug Overdose Deaths After State Policy Changes*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm> (stating that overdose deaths from oxycodone have decreased 52.1%, while overall death rates for prescription drugs have only decreased 23.2%).

¹⁷ Jeffrey Levi et al., *Prescription Drug Abuse: Strategies to Stop the Epidemic 2013* 1, 16, TRUST FOR AMERICA'S HEALTH, (Oct. 2013), http://healthyamericans.org/reports/drugabuse2013/TFAH2013RxDrugAbuseRpt12_no_embargo.pdf.

¹⁸ Alan Schwarz, *Missouri Alone in Resisting Prescription Drug Database*, N.Y. TIMES (July 20, 2014), http://www.nytimes.com/2014/07/21/us/missouri-alone-in-resisting-prescription-drug-database.html?_r=0.

I. PRESCRIPTION DRUG MONITORING PROGRAMS: THE BEST APPROACH FOR LOWERING OPIOID OVERDOSE RATES

In response to increased opioid abuse and overdoses, states have implemented various regulatory initiatives, including anti-doctor-shopping laws, increased Medicaid reimbursement for substance abuse treatment, Good Samaritan laws, Naloxone Access laws, physical exam and ID requirements for opioid prescriptions, Prescription Drug Monitoring Programs, and Pharmacy Lock-in Programs.¹⁹ Many of these initiatives try to prevent abusers from obtaining multiple prescriptions from different providers. Two of the most popular initiatives that impact doctor prescribing and patient access to opioids are anti-doctor shopping laws and Prescription Drug Monitoring Programs.²⁰

Every state in America has an anti-doctor-shopping law, requiring a patient to disclose his or her prescription drug history before receiving another prescription from a different provider.²¹ Anti-doctor shopping laws often deter patients from seeking medically unnecessary opioids from multiple providers.²² However, once the patient discloses the information, the provider has the discretion as to whether to prescribe additional opioids or report suspected abuse. Such laws have a limited impact on reckless physician prescribing practices. For this reason, every state, except Missouri, also has a Prescription Drug Monitoring Program.²³

A PDMP is an electronic database, established and operated by the state, which monitors the prescription and dispensation of controlled substances.²⁴ Legislation authorizing a PDMP often addresses which regulatory actor[s] will create the database and collect and compile the information, as well as the permissible uses of that information.²⁵ A state must also allocate funds for the PDMP, although it can obtain supplemental funds from the U.S. Department of Justice (DOJ) and the Substance Abuse and Mental Health Services Administration (SAMHSA).²⁶

While states' PDMPs vary, they all provide state regulatory bodies, law enforcement officials, or pharmacists and physicians access to information that will hopefully identify potential opioid abusers.²⁷ At least sixteen of the forty-nine states require physicians

¹⁹ Levi et al., *supra* note 17, at 14–15.

²⁰ *Id.* at 16.

²¹ *Id.* at 21.

²² *Id.*

²³ *Id.* at 16.

²⁴ *Id.* at 18.

²⁵ See, e.g., Fla. Stat. § 893.055 (2015).

²⁶ See Levi et al., *supra* note 17, at 38 (detailing SAMHSA's funding of the Health IT Project, which provided states with grants to use health information technology to increase access to PDMP data); Laxmaiah Manchikanti et al., *Evolution of the National All Schedules Prescription Electronic Reporting Act: A Public Law for Balancing Treatment of Pain and Drug Abuse and Diversion*, 8 PAIN PHYSICIAN 4, 335, 336 (2005) (explaining that DOJ manages the Harold Rogers Prescription Drug Monitoring Program, which makes \$11 million available to states to monitor prescription drugs and scheduled listed chemical products).

²⁷ Levi et al., *supra* note 17, at 20 (explaining PDMPs help to identify many sources of prescription drug abuse such as prescription fraud, forgeries, doctor shopping, and improper prescribing and dispensing).

and/ or pharmacists to check a patient's history in a PDMP before enabling that patient to obtain additional opioids.²⁸ PDMPs are particularly effective because they target numerous causal pathways that lead to opioid overdoses — they curb improper doctor prescribing and patient access to opioids, prevent diversion of drugs, and isolate opioid addicts for treatment.²⁹

Opioid overdose deaths have been declining since 2011.³⁰ While PDMPs are not possibly the sole cause of this decrease, they clearly have some positive effect.³¹ PDMPs have been particularly beneficial in Florida and Tennessee. After Tennessee enacted its PDMP in 2013, the state's number of "high utilizers" of opioids (those most at risk for opioid overdose) declined by forty-seven percent.³² Florida, which boasted ninety-eight of the one hundred physicians dispensing the highest volumes of oxycodone in the country in 2010, experienced similar success.³³ After establishing a PDMP in 2011, Florida closed down many of these physicians' "pill mills" and as a result, saw a decline of more than seventeen percent in the number of oxycodone overdose deaths.³⁴

While PDMPs vary, they are more effective when prescribers, pharmacists, and law enforcement have more access to program data.³⁵ When such actors have access to PDMPs, they can better prevent opioid abuse and overdoses.

Brandeis University's Prescription Drug Monitoring Program Center of Excellence³⁶ has drafted a Model Act, which suggests best practices for PDMPs, provisions of which are endorsed by the U.S. Department of Health and Human Services (HHS).³⁷ The Model Act provides that a prescriber or pharmacist should be able to view a

²⁸ *Id.* at 20.

²⁹ *Id.* at 35.

³⁰ See Johnson et al, *supra* note 16, at 570 (reporting a 16.7% decline in drug overdose deaths between 2010 and 2012).

³¹ See *id.* (acknowledging that it is impossible for the CDC to determine which initiatives were most responsible for the decline in drug overdose deaths).

³² *A Nation in Pain*, *supra* note 4, at 21.

³³ Johnson et al., *supra* note 16, at 569.

³⁴ *Id.*

³⁵ See *id.* at 570 (explaining that providers accessed Florida's PDMP 92 times from September through December of 2011, which resulted in a decrease in opioid overdoses).

³⁶ See *About the PDMP Center of Excellence*, Brandeis University, <http://pdmplexcellence.org/about> (explaining that it is "funded by grants from the U.S. Department of Justice and Bureau of Justice Assistance...[, and] collaborates with a wide variety of PDMP stakeholders, including federal and state governments and agencies, universities, health departments, and medical and pharmacy boards").

³⁷ See *HHS takes strong steps to address opioid-related overdose, death and dependence*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (Mar. 26, 2015), <http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html> (hereinafter HHS Press Release) (explaining that the HHS Secretary believes PDMP effectiveness will increase as "states adopt more evidence-based PDMP practices such as collecting data for all controlled substances, proactive reporting to physicians and pharmacists, interstate data sharing, and integration with other health IT systems to improve provider use"); see also Susan Chaityn Lebovits, *Heller Team Helps Fight Prescription Drug Abuse*, BRANDEISNOW (Mar. 5, 2012), <http://brandeis.edu/now/2012/march/drugs.html>.

patient's full record in the PDMP, before prescribing or dispensing additional opioids to the patient.³⁸ Such access helps the prescriber or pharmacist make the (not always clear) distinction between medically necessary treatment and troubling opioid use.³⁹ After viewing the patient's record in the PDMP, the prescriber or pharmacist may also need to obtain additional information from that patient. For example, a patient with multiple opioid prescriptions — might be abusing those drugs or might be struggling to consistently access medical care and needs help managing pain stemming from multiple conditions.⁴⁰ But by accessing the PDMP, a prescriber or pharmacist can at least start the conversation.

The Model Act also provides that each state's PDMP should be interoperable with other PDMPs and electronic health record databases throughout the country.⁴¹ In addition, the Model Act makes a PDMP accessible to medical providers' licensing boards, so they can properly investigate provider misconduct.⁴² Not all states have adopted these updates in the Model Act, but as political pressure intensifies to curb opioid overdoses, more states should make these legislative changes to craft more effective PDMPs.

II. WHAT'S THE DEAL, MISSOURI?

As forty-nine states look for ways to improve the effectiveness of their established PDMPs, the Missouri legislature still refuses to authorize a PDMP.⁴³ Additionally, the Missouri legislature has only adopted three countermeasures to reduce opioid overdose while most states have adopted six or more.⁴⁴ Because of the legislature's refusal to act, in 2010, Missouri had the seventh highest prescription drug overdose mortality rate in the country.⁴⁵ And since 1999, drug overdose deaths in the state have tripled.⁴⁶

³⁸ *Prescription Drug Epidemic: Hearing Before the S. Subcomm. on Crime & Terrorism*, 112th Cong. 4 (2011) (statement of John L. Eadie, Director, Prescription Monitoring Program Center of Excellence) (hereinafter *Prescription Drug Epidemic*).

³⁹ See Christopher A. Griggs, et al., *Prescription Drug Monitoring Programs: Examining Limitations and Future Approaches*, 16 WEST J. EMERG. MED. 67, 68 (2015), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4307729/> (detailing current challenges in evaluating patient data and proposing how to make PDMPs more effective).

⁴⁰ *Id.*

⁴¹ See *Prescription Drug Epidemic*, *supra* note 38, at 5; see also Levi et al., *supra* note 17, at 37 (explaining that for a PDMP to be effective, "healthcare providers and law enforcement agencies [must] be able to share information across state and jurisdictional boundaries").

⁴² *Prescription Drug Epidemic*, *supra* note 38, at 7.

⁴³ See Schwarz, *supra* note 18 (explaining that although many states have a PDMP, the legislation varies as to who has access to the database).

⁴⁴ See Levi et al, *supra* note 17, at 16-17 (explaining that Missouri (1) requires a patient to submit to a physical exam before obtaining a prescription for opioid analgesics; (2) criminalizes the non-disclosure of existing opioid prescriptions to a new provider; and (3) "locks in" any Medicaid beneficiary suspected of misusing controlled substances with a single provider and pharmacist).

⁴⁵ *Id.* at 12. This paper argues that any state benefits from establishing a PDMP that can serve as a central repository of patients' prescriptions for opioids. However, the paper recognizes that other factors, including age, social structure, and poverty— may affect a given state's prescription drug overdose rates. Those other factors are compelling, but beyond the scope of this Article.

⁴⁶ *Id.*

Residents of neighboring states have even started traveling to Missouri to fill their opioid prescriptions.⁴⁷

The lack of a PDMP in Missouri has even brought national attention. In 2012, the Director of the White House's Office of National Drug Control Policy visited Missouri and urged the state legislature to establish a Prescription Drug Monitoring Program.⁴⁸ Some lawmakers have proposed legislation to create a PDMP, but conservatives have struck them down,⁴⁹ citing patient privacy concerns.⁵⁰ However, Missourians are growing tired of the legislature's excuses. For example, in February 2015, activists from the Missouri Network for Opiate Reform and Recovery carried a coffin filled with 1,000 pill bottles bearing the names of victims of fatal overdoses to the state capitol building, to build political pressure.⁵¹

On April 2, 2015, the state senate passed a bill that would authorize a Prescription Drug Monitoring Program.⁵² The legislation died in the Missouri House Select Committee on Insurance,⁵³ but even if it passed, the resulting PDMP would have been largely ineffective. The proposed bill would have authorized the Missouri Department of Health and Senior Services to establish and run a Prescription Drug Monitoring Program.⁵⁴ It would have permitted any provider to report prescriptions for opioids to the database. In contrast, it would have *required* every pharmacist to report every filled prescription to the database.⁵⁵ After submitting information to the database, a pharmacist would have received a response from the department, indicating whether the pharmacist should have any concern about giving the controlled substance to the patient.⁵⁶ If the agency indicated any reason for concern, however, the pharmacist would have been permitted

⁴⁷ Schwarz, *supra* note 18.

⁴⁸ Cameron Hardesty, *Director Kerlikowske Visits Missouri; Urges Adoption of Prescription Drug Monitoring Program*, THE WHITE HOUSE (Aug. 17, 2012 11:17AM), <https://www.whitehouse.gov/blog/2012/08/17/director-kerlikowske-visits-missouri-urges-adoption-prescription-drug-monitoring-pro>.

⁴⁹ *Id.*

⁵⁰ See, e.g., Kyle Loethen, *Missouri Senate Passes Prescription Drug Monitoring*, MISSOURINET (Apr. 6, 2015), <http://www.missourinet.com/2015/04/06/missouri-senate-passes-prescription-drug-monitoring-program/> (citing one senator's disapproval of systems that collect personal data from individuals who have not committed crimes).

⁵¹ Grant Bissell, *Coffin with Pill Bottles Going to the Missouri Capitol*, KSDK (Feb. 23, 2015), <http://www.ksdk.com/story/news/politics/2015/02/24/coffin-with-pill-bottles-going-to-mo-capitol/23922245/>.

⁵² S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015).

⁵³ See *Current Bill Summary: S.B. 63*, MISSOURI SENATE, http://www.senate.mo.gov/15info/BTS_Web/Bill.aspx?SessionType=R&BillID=156 (last visited Jan. 3, 2016) (showing that the last action on the bill was a third reading in the House on May 15, 2015).

⁵⁴ See S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015) (proposing that the agency would use the system to monitor all schedule II-IV controlled substances licensed and prescribed in the state).

⁵⁵ *Id.*

⁵⁶ *Id.* (stating that dispenser will obtain a response from department after transferring information to the database, but not explaining how long it will take to receive such a response).

to use his or her judgment as to whether to prescribe the drug.⁵⁷ The proposed bill also would have imposed numerous regulatory prohibitions on access to the database: it would have prohibited providers and pharmacists from accessing the data⁵⁸; would have disallowed combining information from the database with patient Electronic Health Records data⁵⁹; and would have banned the entry of information from the state PDMP into the national PDMP.⁶⁰

Although the proposed bill represented a huge step forward for the Missouri Senate, it did not follow the PDMP Model Act and if passed, it would have created an ineffective PDMP.⁶¹ The bill did not mandate that providers actually use the database, which researchers believe is a key attribute of a successful PDMP.⁶² Furthermore, denying prescribers and dispensers access to the database would have undermined these professionals' ability to treat their patients, and could have resulted in the unwarranted denial of opioids to patients who need them.⁶³ The proposed bill also would have banned interoperability between the Missouri database and Electronic Health Records⁶⁴ although research suggests that information sharing between EHRs and PDMPs improves physicians' prescribing decisions.⁶⁵ Finally, Missouri's proposed bill would have prevented the PDMP from sharing information with the national database, which would have combated interstate doctor shopping.⁶⁶

III. IS PRIVACY REALLY A BARRIER?

Missouri's proposed bill would have restricted access to the PDMP primarily to "take doctors out of the equation [and not] make them into policemen."⁶⁷ However, public health surveillance activities, such as PDMPs, are not a new form of governance and

⁵⁷ *Id.* (stating that the department will express concern but that it is up to the dispenser to make a final judgment).

⁵⁸ *Id.* (noting that "dispensers and prescribers are not required to access the database and they are only to input data, not access information").

⁵⁹ *Id.* (noting that dispenser and prescriber data will not be mixed with other databases").

⁶⁰ *Id.* (noting that the information will not be linked with other state databases into a national database).

⁶¹ See *Prescription Drug Epidemic*, *supra* note 39, at 4 (recommending several features for a PDMP, which Missouri's proposed bill did not include).

⁶² See, e.g., Levi et al., *supra* note 17, at 16 (giving greater esteem to state laws that mandate PDMP use).

⁶³ See *Prescription Drug Epidemic*, *supra* note 39, at 5 (stating that "PDMPs [should] provide prescription histories to prescribers so they can make clinically sound decisions prior to issuing prescriptions for controlled substances and can avoid being duped by doctor shoppers").

⁶⁴ S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015)

⁶⁵ See Levi et al., *supra* note 17, at 38 (noting that combining electronic health record data and PDMP data improves the quality of prescription drug information available and allows rapid access to such information).

⁶⁶ *Id.* at 37 (arguing that shared information benefits state health systems and that 44 states share PDMP data with other states with 19 states requiring individuals to request the state obtain information from another state).

⁶⁷ Bissell, *supra* note 52.

have been used by public health departments as an effective means to combat both infectious and chronic disease.⁶⁸ Furthermore, courts have resoundingly upheld the legality of surveillance by public health agencies, pharmacists, and providers because patients feel little harm.⁶⁹ These public health activities, however, have not been without controversy. Individuals with the same privacy concerns as the Missouri legislature have unsuccessfully challenged public health surveillance activities under both the Due Process Clause and the Health Insurance Portability and Accountability Act.⁷⁰

Missouri legislators opposing establishment of a PDMP have posited that such programs abridge individuals' freedoms.⁷¹ Such liberty concerns are generally analyzed under the Due Process Clause.⁷² However, the Supreme Court resolved such privacy arguments in 1977.⁷³ In *Whalen v. Roe*, the Supreme Court held that the Due Process Clause protected an individual's right to privacy in his or her health information, but ultimately upheld the government's collection of health information so long as it was adequately secured.⁷⁴ In later decisions, courts interpreted *Whalen* as conferring a limited right to privacy.⁷⁵ Courts now evaluate public health surveillance activities by balancing an individual's privacy interest against the government's interest in collecting the

⁶⁸ See, e.g., LAWRENCE O. GOSTIN & LINDSEY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY & RESTRAINT—CHAPTER 9: SURVEILLANCE & PUBLIC HEALTH LAW 28 (forthcoming 2016) (hereinafter Gostin & Wiley, *Surveillance & Public Health Law*) (explaining that in 2006, the New York City Board of Health responded to a diabetes epidemic by requiring laboratories (but not physicians) to report hemoglobin A1C test results to the city).

⁶⁹ See Lawrence O. Gostin, "Police" Powers and Public Health Paternalism: HIV and Diabetes Surveillance, 37 HASTINGS CENT. REP. 9, 10 (2007) (arguing that patients have limited ammunition in their arguments over the privacy aspects of public health data because of the many benefits that such disclosures can bring).

⁷⁰ See, e.g., *Whalen v. Roe*, 429 U.S. 589 (1977).

⁷¹ See, e.g., Loethen, *supra* note 50 (citing one state senator's argument that "whenever you take an innocent person's information and put it in a database[,] that takes away their liberty that takes away their freedoms").

⁷² Loethen, *supra* note 50.

⁷³ See *Whalen*, 429 U.S. at 603-604 (upholding a New York statute that required prescriptions of Schedule II drugs to be prepared on an official form, which identified the patient's name and address).

⁷⁴ See *id.* at 601 (holding that the impact of the release of patient identification on their reputation and independence was not sufficient to constitute an invasion of their Fourteenth Amendment privacy rights).

⁷⁵ See, e.g., *Nixon v. Adm'r of Gen. Servs.*, 433 U.S. 425, 457-459 (1977) (stating that when there is a government interest at stake, any disclosure of private matters must be weighed against the public interest); *Planned Parenthood v. Danforth*, 428 U.S. 52, 80 (1976) (advocating that recordkeeping and reporting mandates aimed at preserving the mother's health are permissible if they respect patient privacy); *Rasmussen v. S. Fla. Blood Serv., Inc.*, 500 So. 2d 533, 535 (Fla. 1987) (reaffirming the two privacy interests in *Whalen*, the individual interest in avoiding the dissemination of private matters and the interest in preserving independence in making important decisions).

data.⁷⁶ Since HHS has declared opioid abuse to be a national epidemic,⁷⁷ the Missouri government most likely has a compelling interest in authorizing a Prescription Drug Monitoring Program. Furthermore, patients feel little harm if information is only shared between medical providers and public health agencies.⁷⁸ Also, most authorizing legislation for PDMPs, including the Missouri Senate Bill⁷⁹, requires data collected by government agencies to be encrypted, which would limit the risk of privacy breaches and meet the adequate surveillance test enunciated in *Whalen*.⁸⁰

It is clear, under the prevailing balancing test for evaluating public health surveillance, that Missouri's interest in opioid prescribing information would outweigh any invasion of patients' privacy and would justify the Missouri Senate's proposed PDMP legislation. Missouri's legislature could even pass more robust legislation, which would share the PDMP's information with providers, without violating health information privacy protections conferred by the Due Process Clause.

Opponents of PDMPs also argue that PDMPs violate privacy laws. However, the federal privacy law, the Health Insurance Portability and Accountability Act (HIPAA),⁸¹ and Missouri's privacy regulations⁸² both authorize protected health information to be authorized for patient treatment and public health surveillance purposes.

Upon passing HIPAA in 1996, Congress directed the Secretary of HHS to promulgate final regulations "governing standards with respect to the privacy of individually identifiable health information" within 42 months of the enactment of the Act.⁸³ In response, HHS published its final privacy rules in December of 2000.⁸⁴ The privacy regulations only

⁷⁶ See, e.g., *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 578 (3d Cir. 1980) (establishing the balancing factors to be considered when justifying whether to intrude on an individual's privacy: type of record requested; the information it does or may contain; potential harm resulting from nonconsensual disclosure; injury resulting from disclosure to the relationship in which the record was generated; adequacy of the safeguards to prevent disclosure; the urgency of need for access; and the existence of a statutory, public policy, or public interest justification for access).

⁷⁷ See HHS Press Release, *supra* note 37.

⁷⁸ See Gostin, *supra* note 69, at 10 (arguing that patients are not impacted by this intrusion on their privacy).

⁷⁹ S.B. 63, 98th Gen. Assemb., Reg. Sess. (Mo. 2015). (stating that "all communications and data transmitted [to and from the proposed PDMP] shall be encrypted").

⁸⁰ See Gostin & Wiley, *Surveillance & Public Health Law*, *supra* note 68, at 16 (explaining that the *Whalen* court determined that the state had adequate security measures in place, such as keeping computer tapes in a locked cabinet, operating the computer off-line to prevent unauthorized access, and disclosing data to only a limited number of officials).

⁸¹ 45 C.F.R. § 164.502(a) (2014); 45 C.F.R. § 164.512(b) (2014); see also Richard Sobel, *The HIPAA Paradox: The Privacy Rule That's Not*, 37 HASTINGS CENT. REP. 40, 40 (Aug. 2007) (explaining that the HIPAA Privacy Rule is not absolute, but rather, sets forth which disclosures are required and permitted).

⁸² Mo. Code Regs. Ann. tit. 13, §§ 70-1.010 *et seq.* (2015).

⁸³ The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 264, 110 Stat. 2033, 104th Cong. (1996).

⁸⁴ 45 C.F.R. §§ 160, 164 (2000).

apply to “covered entities” (including doctors, pharmacists, and HMOs)⁸⁵, and prohibit these entities from disclosing “protected health information” (PHI)⁸⁶ without patient permission unless a regulatory exception applies. Covered entities, however, may share “de-identified information” and can sometimes permissively disclose PHI.⁸⁷ HIPAA authorizes permissive disclosure of PHI for “public health activities,”⁸⁸ and so, the creation of a public health surveillance system to monitor opioid prescriptions would be permitted under federal regulations. In the Final Rule, HHS explained that it permitted these exceptions because an individual’s right to privacy is “not absolute.”⁸⁹

However, HIPAA is only a “floor” of legal protection over each individual’s protected health information; any state may pass more restrictive legislation if it chooses.⁹⁰ Therefore, it is necessary to analyze whether a particular state’s privacy laws would authorize a PDMP. Missouri has similar, but arguably stricter, privacy regulations in comparison to HIPAA.⁹¹ Missouri mandates disclosure of contagious disease, firearm injuries, medication reactions, work-related injuries, and birth and death information; however, it does not have a broad authority for permissive disclosure of “public health activities.”⁹² The number of authorities for mandatory disclosure of PHI in the Missouri regulations is significant and reflects the notion that the state must overcome individuals’ privacy concerns in order to address threats to public health. However, under the Missouri regulations, disclosure of PHI related to opioid prescriptions could not be disclosed to the

⁸⁵ 45 C.F.R. § 160.103 (2000) (defining a “covered entity” as “(1) a ‘health plan; (2) a health care clearinghouse; (3), a health care provider who transmit any health information in electronic form in connection with a transaction covered by . . . the” Act).

⁸⁶ 45 C.F.R. § 160.103 (defining protected health information as “is individually identifiable health information . . . [t]ransmitted or maintained . . . transmitted in any form or medium,” but excluding educational and employment records... Health information must “[r]elate to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual”).

⁸⁷ See generally 45 C.F.R. § 164.510 (2000) (listing the “Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required”).

⁸⁸ 45 C.F.R. § 164.512(b) (allowing disclosure of PHI “without individual authorization to: (1) A public health authority authorized by law to collect . . . such information for purpose of preventing or controlling disease, injury, or disability, including . . . reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, . . . and public health interventions; . . .”).

⁸⁹ 45 C.F.R. § 160 (“It does not, for instance, prevent reporting of public health information on communicable diseases or stop law enforcement from getting information when due process has been observed”).

⁹⁰ Lawrence O. Gostin & Lindsay F. Wiley, *Public Health Law: Power, Duty, Restraint, Chapter 3: Public Health In the Constitutional Design*, 3 (forthcoming 2016) (explaining that HIPAA, similar to federal civil rights and consumer protection laws, achieves “floor preemption” because it only preempts state and local laws that fall short, however, states and localities are permitted to pass more robust laws if they choose).

⁹¹ Mo. Code Regs. Ann. tit. 13, § 70-1.010 (2015).

⁹² Mo. Code Regs. Ann. tit. 13, § 70-1.020(3)(B) (“The Department of Social Services, MO HealthNet Division shall provide information—1. To public health authorities to report contagious and reportable disease, including but not limited to . . . birth defects, cancer, or other information for public health purposes; 2. Reporting of certain types of wounds or other physical injuries...”). . . .”).

Missouri Department of Health and Senior Services under their mandatory disclosure authority, which is limited to specific public health surveillance purposes.⁹³

However, both HIPAA and the Missouri privacy regulations permit disclosure of protected health information for “treatment” purposes. HIPAA provides that a covered entity (e.g., a physician or hospital) *may* disclose protected health information about an individual in order to treat the individual, and can consult with other health care providers about courses of treatment.⁹⁴ The Missouri regulations also permit the disclosure of PHI for treatment purposes in accordance with HIPAA.⁹⁵ The Missouri regulations provide an expansive definition of what “treatment” warrants PHI disclosure.⁹⁶

Furthermore, the Missouri Senate Bill’s proposed PDMP would not have violated HIPAA or the Missouri regulations, because it would have only required pharmacists and permitted providers to use the database for treatment purposes (e.g., deciding whether to fill prescriptions for opioids). If the Missouri legislature goes further and creates a PDMP following the Model Act, that would not violate HIPAA or the state’s privacy regulations because the PDMP’s central purpose would be to identify and treat patients who are addicted to opioids.⁹⁷

CONCLUSION

The Missouri legislature’s inability to pass a PDMP has contributed to increasing opioid overdose rates in both Missouri and surrounding states.⁹⁸ But as a late adopter of this public health measure, the state legislature also has a unique opportunity to build on evidence-based practices to craft a resoundingly effective PDMP. Unfortunately, the state senate passed a largely toothless bill that the house rejected, allegedly because of concerns with patient privacy.⁹⁹ But these concerns are unfounded, as the right to patient privacy is not absolute,¹⁰⁰ and even the most expansive PDMP legislation (e.g., the

⁹³ *Id.*

⁹⁴ 45 C.F.R. § 164.501 (2000) (explaining that “disclosure of protected health information for treatment of any health care provider may include a provider sending a copy of an individual’s medical record to a specialist who needs the information to treat the individual”).

⁹⁵ Mo. Code Regs. Ann. tit. 13, § 70-1.020(4) (“The Department of Social Services . . . may disclose, at its discretion, a participant’s protected health information to designated business associates in accordance with and as authorized by HIPAA . . .”).

⁹⁶ Mo. Code Regs. Ann. tit. 13, § 70-1.020(4)(B) (“Treatment of a Participant. Includes activities such as, providing, coordinating, or managing health care delivery and related services; consultation between providers relating to a participant; referral of a participant to another provider for health care; and necessary sharing of information through a health information network for treatment purposes . . .”).

⁹⁷ Levi et al., *supra* note 17, at 20 (explaining that by creating a PDMP and requiring providers and prescribers to use it, a state can prevent and treat opioid abuse).

⁹⁸ *Supra* notes 45-47 and accompanying text (discussing that Missouri has the seventh highest opioid mortality rate and that patients from contiguous states go to Missouri to purchase opioids).

⁹⁹ See *supra* notes 48-60 and accompanying text (evaluating the proposed bill).

¹⁰⁰ See, e.g., Gostin, *supra* note 69, at 10 (arguing that “justice [does not require] government to leave people utterly alone, free to act in ways that cause severe disability and premature death”).

PMP Model Act) does not violate the privacy protections afforded by the Constitution, HIPAA, and Missouri state regulations.¹⁰¹

Unfortunately, patient privacy protections are not the only barrier to passing authorizing legislation in Missouri; some of the state's conservative lawmakers also seem generally distasteful of people addicted to drugs.¹⁰² However, such lawmakers should overcome such biases and join the national fight against opioid overdoses. Since Missouri does not have a PDMP, its legislature could and should adopt a PDMP similar to the PDMP envisioned in the Model Act.¹⁰³ The legislature must mandate, consistent with the Model Act, that both prescribers and pharmacists have full access to the database and must report each prescription written or dispensed to the database.¹⁰⁴ The Act should also permit interoperability with the state's electronic health records system and the national prescription monitoring database to help doctors better treat their patients and to combat interstate doctor shopping.¹⁰⁵ By adopting these measures, Missouri will see a significant reduction in opioid overdoses and could become a national leader in the fight against opioid overdose.

¹⁰¹ See *supra* notes 67-95 and accompanying text.

¹⁰² See Schwarz, *supra* note 18 (quoting Missouri Senator Robert Schaff, a leading opponent of creating a PDMP, in 2012: "if [drug abusers] overdose and kill themselves, it just removes them from the gene pool").

¹⁰³ *Prescription Drug Epidemic*, *supra* note 38, at 3-4.

¹⁰⁴ *Id.* at 4-5.

¹⁰⁵ *Id.* at 4.